CARDIOHELP System
510(k) Summary
Prepared in accordance with 21 CFR Part 807.92

GENERAL INFORMATION

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Date prepared: November 21, 2013

DEVICE INFORMATION:

Trade Name:	CARDIOHELP System, Model CARDIOHELP-i
Common/Generic Name:	Cardiopulmonary Support System
Classification Name:	Cardiopulmonary bypass heart/lung machine console
Regulation Number:	21 CFR 870.4220
Product Code:	DTQ

PREDICATE DEVCE INFORMATION:

The modified CARDIOHELP System is substantially equivalent in function and intended use to the CARDIOHELP System (K102726).

DEVICE DESCRIPTION AND INTENDED USE:

The CARDIOHELP System is a compact perfusion system consisting of the following components:

- the CARDIOHELP-i drives suitable disposables using an integrated pump, controls and monitors the extracorporeal circulation and can communicate with other devices
- the CARDIOHELP Emergency Drive is used in emergencies to manually drive the disposable if the CARDIOHELP-i fails
- different accessories:

  - flow/bubble sensor
  - level sensor including level sensor pad
  - venous probe for blood gas monitoring and measurement of venous temperature
  - external sensors for temperature and pressure
  - different holders
  - connection cables
- various disposables, that can be driven by CARDIOHELP-i, including the previously cleared HLS/HIT tubing sets and the Quadrox-iR disposables (part of the predicate CARDIOHELP System (K102726).

Indications for Use:
The CARDIOHELP System is a blood oxygenation and carbon dioxide removal system used to pump blood through the extracorporeal bypass circuit for circulatory and/or pulmonary support during procedures requiring cardiopulmonary bypass (for periods up to six hours). It is also intended to provide circulatory and/or pulmonary support during procedures not requiring cardiopulmonary bypass (for periods up to six hours).

The CARDIOHELP System in configuration with the HLS/HIT Set Advanced is intended to be used within the hospital environment and outside the hospital environment (for periods up to six hours), e.g. for intra- and inter-hospital transport.

The CARDIOHELP System in configuration with the QUADROX-iR is intended to be used in extracorporeal circulation during cardiopulmonary bypass in cardiac surgery (for periods for up to six hours).

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS TO PREDICATES:

The modified CARDIOHELP system is substantially equivalent to the predicate CARDIOHELP System (K102726). The modification essentially consists of an enhanced user interface, new sensors for detection of bubbles and additional sensor sizes for temperature and flow bubble sensor, venous probe with compatibility for additional sizes, and adding emergency mode key button to provide the user the capability to use the CARDIOHELP System without a touch screen.

NON-CLINICAL TESTS:

Performance testing has resulted in data that demonstrates that the CARDIOHELP System performs within its specifications and within the acceptable limits of the applied performance standards. The following performance characteristics of the CARDIOHELP System were extensively compared with the predicate devices to determine substantial equivalence:

- Requirements specification review
- Hardware and software testing
- Code design and code reviews
- Environmental testing
- Safety testing
- Performance testing
- Hardware and software validation

CLINICAL TESTS:

No clinical evaluation of the modified device was conducted or required.

CONCLUSION:

Based upon the information submitted in this Special 510(k) premarket notification, MAQUET's modified CARDIOHELP System is substantially equivalent to the currently marketed CARDIOHELP System (K102726). The modified CARDIOHELP System is similar to the predicate device in the intended use, the fundamental scientific technology of the device. The device is as safe and effective and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 21, 2014

Maquet Cardiovascular
Helder Sousa
Regulatory Affairs Program Manager
45 Barbour Pond Drive
Wayne, NJ 07470

Re: K133598
Trade/Device Name: CARDIOHELP System, Model CARDIOHELP-i
Regulation Number: 21 CFR 870.4220
Regulation Name: Cardiopulmonary Support System
Regulatory Class: Class II
Product Code: DTQ
Dated: April 16, 2014
Received: April 17, 2014

Dear Mr. Sousa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K133598

Device Name: CARDIOHELP System

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)